

calcium salt; 2-pyrrolidone-5-carboxylate derivatives of amino acids; and 2-pyrrolidone-5-carboxylic laurate.

B² cont
40. A composition according to claim 14 wherein the means to retain water in the outer skin layer is a urea.

41. A composition according to claim 17 wherein the inorganic salt is sodium chloride.--

REMARKS

Claims 14-38 are pending in the instant application all of which stand rejected. Applicants have hereby amended claim 14 to more specifically describe the carboxylic acid as set forth on page 4, lines 13-25 and have added new claims 39 – 41, support for which can be found in the specification as follows:

Claim 39 – page 4, lines 13-24; claim 40 – page 4, lines 28-30; and claim 41 – page 4, lines 11-12.

It is submitted no new matter has been added by the present amendment.

Applicants respectfully request reconsideration of the application and allowance of the claims in view of the foregoing amendments and following remarks.

The rejection of claims 14-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is respectfully traversed. It is the Examiner's position that "the word 'means' is preceded by the words 'to retain water' in an attempt to use a means clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding 'means,' it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph." The word "means" is not preceded by the words 'to retain water' but rather those words follow it. Contrary to the Examiner, a function is clearly set forth, i.e. retaining water in the outer skin layer. The specification, at page 4, first full paragraph, clearly sets forth specific materials for performing the function. The Examiner's reliance on *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967) is not understood. As clearly set forth therein, "so long as the modifier of that term [means] specifies a function to be performed", means plus function language is in conformity with the statute (see page 695, second column under section 21). Accordingly, applicants submit the claims are definite within the meaning of 35 USC 112, second paragraph.

The rejection of claims 14-38 under 35 U.S.C. 103(a) as being unpatentable over Asakura et al (US 5,385,907) in view of Baumann et al (US 5,352,671) is respectfully traversed.

The present invention is directed to a composition for topical administration of an ascomycin for treatment of skin disorders which comprises a carrier vehicle comprising a means to retain water in the outer skin layer and a means to hinder water evaporating from the skin. The means to retain

water comprise a urea, an inorganic salt, or a carboxylic acid wherein the carboxylic acid is selected from a carboxylic acid or derivative thereof selected from the group consisting of a cyclic carboxylic acid or salt thereof; lactic acid; glycolic acid; lactic acid sodium and/or ammonium salt; glycolic acid sodium and/or ammonium salt; lactamide; lactamidopropyl-triammonium chloride; and sodium cocoyl lactylate.

Asakura et al. discloses compositions of ascomycins comprising solubilizing and/or absorption promoting agents as set forth in column 5, lines 41 to 60, topromote absorption of the drug. There is no teaching or suggestion of a means to retain water in the outer skin layer nor a means to hinder water evaporating from the skin. Applicants have amended claim 14 to more particularly define the carboxylic acid and more clearly distinguish it from Asakura et al.

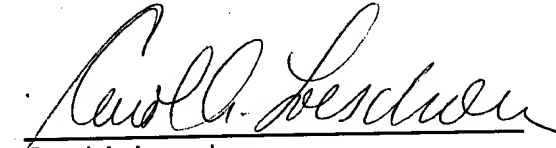
Baumann et al. specifically discloses the ascomycin of claim 15 and does not make up for the deficiencies of Asakura et al.

For the reasons set forth above, it is respectfully submitted that the instant claims are patentable over the cited art. Accordingly, reconsideration of the application and allowance of the claims is respectfully requested.

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Authorization is hereby given to charge the additional claim fee of \$54.00 (37 CFR 1.16(c)) for the 3 dependent claims to Deposit Account No. 19-0134 in the name of Novartis Corporation. An additional copy of this page is being submitted herewith for purposes of charging such fee.

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

14. (amended) A composition for topical administration of an ascomycin for treatment of skin disorders which composition comprises a carrier vehicle comprising

- (i) means to retain water in the outer skin layer comprising a urea, an inorganic salt, or a carboxylic acid, wherein said carboxylic acid is a carboxylic acid or derivative thereof selected from the group consisting of a cyclic carboxylic acid or salt thereof; lactic acid; glycolic acid; lactic acid sodium and/or ammonium salt; glycolic acid sodium and/or ammonium salt; lactamide; lactamidopropyl-triammonium chloride; and sodium cocoyl lactylate and
- (ii) means to hinder water evaporating from the skin.